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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,537	04/08/2004	Sudhir V. Shah	2629.1003-011	8841
21005	7590	09/10/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,537

Applicant(s)

SHAH, SUDHIR V.

Examiner

Randall Winston

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0404 and 0204</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claims indicates that claim 1 is drawn to a genus of an "iron chelator".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a

substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed 1 genus disclosed within the specification that is within the scope of the claimed genus of an "iron chelator". The specification on page 10 lines 3-7 discloses the single species such as "deferiprone" that is within the claimed genus of an "iron chelator".

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim 1 encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises of an "iron chelator".

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method for treating the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis comprising the steps of administering a dose of a deferiprone to a human suffering from the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis (see, e.g. Example 2 and Table 3), the specification does not enable any person in the art for preparing a method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the

Art Unit: 1654

art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria. Applicant has reasonably demonstrated in example 2 and Table 3 of the specification a method for treating the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis comprising the steps of administering a dose of a deferiprone to a human suffering from the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria. For example, Abraham et al. teach (Derwent Acc-No 1990-163991, abstract) a method of treating diabetic nephropathy in a human comprising the steps of administering a dose of an hydroxamic acid derivative to a human suffering from diabetic nephropathy (see, also Durantton et al. US 20030064929

Art Unit: 1654

that teaches in claim 18 that hydroxamic acid derivatives are iron chelating compounds). Thus, the art is silent regarding the efficacy of applicant's method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria. Therefore, applicant's claimed method is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated in example 2 and Table 3 of the specification a method for treating the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis comprising the steps of administering a dose of a deferiprone to a human suffering from the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for treating microalbuminuria in a human comprising the steps of administering a dose of any/or all iron chelators to a human suffering from microalbuminuria.

Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Please Note claims 1-3 are free of the art because there is no motivation in the prior art to prepare a method for treating the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis comprising the steps of administering a dose of a deferiprone to a

Art Unit: 1654

human suffering from the kidney diseases of diffuse proliferative glomerulonephritis, membranoproliferative glomerulonephritis and focal segmental glomerulosclerosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PATRICIA LEITH
PRIMARY EXAMINER